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ART UNIT	**PAPER NUMBER**
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,744	ROBERTSON ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *11,25,26 and 31-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-24 and 27-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-10, 12-24 and 27-30 in the paper filed on March 16, 2007 is acknowledged.

Applicants argue that unity of invention exists between the restricted Groups as claims are directed to the same invention (response, page 2, lines 6-9).

Applicant's argument was fully considered but was not found persuasive. It must be noted that instant Application is a national stage entry of a PCT Application (PCT/CA03/01754 filed 11/14/200) under 35 U.S.C. 371 and is subjected to restriction requirement under 35 U.S.C. 121 and 372. Furthermore, the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art, for the reasons of record stated in the Office action mailed on 12/18/2006. Accordingly, claims 1-10, 12-24 and 27-30 are examined on merits in the instant Office action. Claims 11, 25-26, and 31-52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Elected claims must be amended to remove non-elected subject matter. This restriction is made FINAL.

Applicant are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed on 06/29/2006 is attached to the instant Office action.

Specification

The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See for example, page 20, lines 10-11; page 27, line 10. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate action/corrections are required.

Drawings

The drawings are objected to because of the following informalities:

Drawings are objected to because they fail to comply with 37CFR 1.83.

4. Figures 5a, 6 (left panel), 7a, 7b, 8a-8c, 9a-9d, 10a-10b, 11a, 12a-12b, 13a-13c, 14a-14c, 15a-15c, 16a, 17a-17c, 18a, 19a-19b, 20a-20c, 21a-21c, 23a-23b, 24a-24b, 25a-25b, 26a-26c, 27a-27b, 29a-29b, 30a-30b, 31, 33a-33b, 34, 35a-35b, 37a and 37b fail to comply with 37 CFR 1.84(g) because these figures are framed.

5. Figures 1-37 are informal because they are hand-written corrections. These must be replaced with typed text using appropriate font size. Parts of figures must be identified in their brief description to drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate corrections are required.

Claim Objections

6. Claims 2-8, 10, 20, 22-23, 27, 29 and 30 are objected to because of the following informalities:

In claim 2, line 4, replace "peptide" with --polypeptide--.

In claims 2-6, replace "a complement" with --full complement-- because "a complement" reads on 2 mer sequence.

In claim 2, line 8; claim 6, line 8; claim 10, line 3; claim 21, line 3; claim 29, line 3; claim 30, line 3 replace "compared to an unmodified plant" with --as compared to an untransformed plant of the same species--.

In claims 3-5, line 3, insert --protein encoded by-- after "to the" and before "ROB5 gene".

In claims 7, 8, 22, and 23 insert --as compared to an untransformed plant of the same species-- at the end of claims.

Claim 27 is objected for depending from a non-elected claim 26.

Appropriate action/corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10, 12-24, and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "ROB5", which is confusing, since it is unclear what the recitation stands for? The specification does not define "ROB5". It is unclear which sequences besides SEQ ID NO: 1 and its encoded protein of SEQ ID NO: 2 are encompassed by the recitation and which are not. It is unclear what is intended?

Claims 2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "a transgenic plant exogenously expressing said nucleotide sequence compared to an unmodified plant", which is confusing since it is unclear how a transgenic plant can exogenously express a nucleotide sequence. A nucleotide sequence is expressed within a plant cell. It is unclear what is intended?

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "encoded by the nucleotide sequence of a), or a complement thereof" in line 5, and "said nucleotide sequence or complement thereof encodes a protein or a part thereof" in line 6, which is confusing since it is unclear how a complementary sequence of a coding sequence would encode the same protein or polypeptide. The complementary sequence would either encode no protein or encode a different protein. It is unclear what is intended?

Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "encodes a protein or a part thereof" in lines 2-3 of claims 3-5, and line 6 of claim 6, which is confusing since it is unclear how a complementary sequence of a coding sequence would encode the same protein or polypeptide. The complementary sequence would either encode no protein or encode a different protein. It is unclear what is intended?

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "complement thereof" in line 4, which is confusing since it is unclear how a complementary sequence of a coding sequence would encode the same

protein or polypeptide. The complementary sequence would either encode no protein or encode a different protein. It is unclear what is intended?

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "stringent conditions", which is confusing since it is unclear what level of stringency is encompassed by "stringent conditions". Page 21 of specification gave examples but did not define "stringent conditions".

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "adverse", which is confusing since it is unclear which "adverse" conditions are being referred to. Also metes and bounds of the recitation are unclear and not defined. Are applicants referring "adverse" conditions of environment or anything else?

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "a construct comprising a vector" which is confusing since it is unclear how a construct can comprise a vector? Page 22 of specification describes a "DNA construct" as "a nucleic acid molecule that is isolated from a naturally occurring gene or which has been modified to contain segments of nucleic acid which are combined and justaposed in a manner which would not normally otherwise exist in nature". A vector is supposed to comprise a construct. It is unclear what is intended?

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "derived", since it is unclear what is retained in the derived product. It is suggested to replace "derived" with --obtained--.

Claim 20 and claims dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claims are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 20 is missing the essential step of expressing the nucleotide sequence. The last step only results in a plant comprising a construct.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it is unclear whether the claims are directed to a product or process.

Dependent claims 7-9, 12, 14-16, 18-19, 21-24, and 27-28 are also rejected because they fail to overcome the deficiencies of the claim(s) they depend on.

Appropriate action/corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-10, 12-24, 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleotide sequence encoding a ROB5 protein as defined in SEQ ID NO: 2, transgenic plant and a method of making said transgenic plant comprising said nucleotide sequence, does not reasonably provide enablement for (a) a nucleotide sequences encoding a protein which has less than 100% sequence identity to the protein encoded by SEQ ID NO: 1, (b) a complement of SEQ ID NO: 1 encoding a protein, (c) any ROB5 protein or fragment

thereof, (d) a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO: 1 or a complement thereof, and (e) a part of protein encoded by SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claims are broadly drawn to an isolated nucleotide sequence or a complement thereof encoding a ROB5 protein, transgenic plant cell, plant or a method of genetically modifying a plant comprising said nucleotide sequence, and wherein said protein alters a stress response and/or growth potential of a transgenic plant comprising said nucleotide sequence.

The specification as filed teaches isolation of a nucleotide sequence (SEQ ID NO: 1) encoding a ROB5 protein as defined in SEQ ID NO: 2. The nucleotide sequence was isolated through screening an expression cDNA library prepared from Broom grass cells (Examples 1 and 2). The specification further teaches frost, heat and drought

tolerant canola, flax and potato plants expressing said nucleotide sequence. The specification further teaches that said transgenic plants exhibited faster germination and seedling emergence compared to an untransformed control plant. Furthermore, specification also teaches that said transgenic plants matured earlier compared to untransformed control plants. See pages 36-43, Examples 6-20. Field trial evaluations of said transgenic canola and flax plants are also taught. See pages 45-53.

Claim 1 is directed to an isolated nucleic acid sequence encoding a fragment of any ROB5 protein, claim 2 is directed to a nucleotide sequence encoding a peptide which has at least 50% sequence identity to the peptide encoded by SEQ ID NO: 1, claim 2 is also directed to a nucleotide sequence encoding a part of protein encoded by SEQ ID NO: 1, claim 3 is directed to a nucleotide sequence encoding a protein which has at least 70% sequence identity to the protein encoded by SEQ ID NO: 1, claim 4 is directed to a nucleotide sequence encoding a protein which has at least 90% sequence identity to the protein encoded by SEQ ID NO: 1, and claim 5 is directed to a nucleotide sequence encoding a protein which has at least 95% sequence identity to the protein encoded by SEQ ID NO: 1. This implies that these claims and claims dependent thereon encompass nucleotide sequence(s) which would encode protein having less than 100% sequence identity to the ROB5 protein defined in SEQ ID NO: 2. The claims encompass substitutions, additions, deletions of one or more nucleotides in the nucleotide sequence of SEQ ID NO: 1, implying that the encoded proteins derived from such sequence(s) would comprise addition, substitutions or deletions of one or more amino acids in the functionally established ROB5 protein encoded by SEQ ID NO: 1 and

further as defined in SEQ ID NO: 2. The specification clearly provides guidance on expressing a nucleotide sequence encoding the protein of SEQ ID NO: 2 in a variety of different transgenic plants which exhibited abiotic stress tolerant phenotype(s) as discussed above. However, specification does not provide guidance on using sequences encoding protein which has less than 100% sequence identity to instant SEQ ID NO: 2 in a method of producing stress tolerant plant(s). The specification also does not provide guidance on using fragment(s) of SEQ ID NO: 2 or ROB5 protein in a method of obtaining plants with improved characteristics, such as stress tolerance and/or improved growth and development.

While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see for example, Wells, Biochemistry 29:8509-8517, 1990; Ngo et al., The Protein Folding Problem and Tertiary Structure Prediction, K. Merz., and S. Le Grand (eds.) pp 492-495,1994). Furthermore, Keskin et al. (Protein Science, 13:1043-1055, 2004) teach that proteins with similar structure may have different functions. Besides, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000) teach that structural data

may carry information about the biochemical function of the protein. It's biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions. Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as at least 50% to 95% sequence identity to the protein encoded by SEQ ID NO: 1 would encompass significant changes in the ROB5 protein of SEQ ID NO: 2, except changes due to codon degeneracy. For example, Buell et al. (NCBI, GenBank Sequence Accession No. Q8S7U3, Published 2002) teach a nucleotide sequence encoding an unrelated embryo-specific protein which has 54% sequence identity to ROB5 protein of SEQ ID NO: 2. Neither the state of art nor Applicants provide guidance as to how inoperable embodiments could have been readily eliminated other than random trial and error. The additions, deletions or substitutions in one or more amino acid residues would also encompass changes in the functionally important domain(s) of the encoded protein. In the absence of guidance, it would have been highly unpredictable at the time the claimed invention was made that a nucleotide sequence encoding a part of SEQ ID NO: 2 or a polypeptide having at least 50%-95% sequence identity to the ROB5 protein encoded by SEQ ID NO: 1 would encode a functionally active protein which would have resulted in the increased stress tolerance response and/or improved growth potential when expressed in a transgenic plant. In the absence of adequate guidance, undue experimentation would have been required by a skilled artisan at the time claimed

invention was made to determine how to use a nucleic acid sequence encoding a protein which has less than 100% sequence identity to the protein encoded by SEQ ID NO: 1, in a method of producing a transgenic plant with increased stress tolerance response and/or improved growth potential. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim 1 is directed to any ROB5 protein. The specification clearly teaches the cDNA of SEQ ID NO: 1 encoding a ROB5 protein as defined in SEQ ID NO: 2. The breadth of the claim encompasses any ROB5 protein from any source. In the absence of guidance, undue experimentation by one skilled in art would have been required to isolate nucleotide sequence(s) encoding ROB5 protein(s) from other sources and use them in a method to produced expected results, such as stress tolerant transgenic plant. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Claim 1 is directed to altering (increase and/ or decrease) a stress (abiotic and or biotic) and / or growth potential. Claims 7 and 22 are directed to increased resistance to pests and diseases, claims 8 and 23 are directed to slower growth rate and smaller biomass of a transgenic plant comprising SEQ ID NO: 1. The specification provides

guidance on abiotic stress tolerant properties of SEQ ID NO: 1 encoding ROB5 protein of SEQ ID NO: 2. The specification does not provide guidance on biotic stress tolerance and/or slower growth rate and smaller biomass properties of SEQ ID NO: 1 when expressed in a transgenic plant. In the absence of guidance, undue experimentation would have been required by a skilled artisan at the time the claimed invention was made to determine how to use SEQ ID NO: 1 in a method of producing a transgenic plant with increased biotic resistance and slower growth rate and/or smaller biomass.

Claims 16-24 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Product that is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claims 16-24 do not mention expressing the nucleotide sequence in the plant cell or plant. See MPEP 2164.089(c).

Claim 6 is directed to any nucleotide sequence or complement thereof that hybridizes to the nucleotide sequence of SEQ ID NO: 1 or a complement thereof because the stringent conditions described on page 21 of specification would encompass hybridization of a nucleotide sequence that is unrelated to SEQ ID NO: 1. This implies that sequences, which do not encode a protein, or encode a protein, which is unrelated to ROB5 protein of SEQ ID NO: 2 would also hybridize under said conditions of hybridization. In the absence of adequate guidance, undue experimentation would have been required by one skilled in the art to determine how to

use said unrelated sequences in a method of producing a transgenic plant with altered stress response and / or growth potential.

Claims 2-6 are directed to a complement of SEQ ID NO: 1 encoding a protein with stress tolerance properties. A complement of SEQ ID NO: 1 would either encode no protein or encode a protein that is unrelated to ROB5 protein of SEQ ID NO: 2. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to use a complement of SEQ ID NO: 1 in a method of providing stress tolerance properties when expressed in the transgenic plant.

Claim 28 is directed to a portion of SEQ ID NO: 1 amplified by a pair of primers annealing to SEQ ID NO: 1 anywhere in its full-length sequence. This implies that the amplified fragment would not encode a full-length protein of SEQ ID NO: 2. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to use said amplified fragment(s) encoding a portion of SEQ ID NO: 2, in a method of altering stress response and/or growth potential in a transgenic plant expressing said amplified fragment.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention. Therefore, it is maintained that the claimed invention is not enabled as commensurate in scope with the claims.

9. Claims 1-10, 12-24, 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to an isolated nucleotide sequence or a complement thereof encoding a ROB5 protein, transgenic plant cell, plant or a method of genetically modifying a plant comprising said nucleotide sequence, and wherein said protein alters a stress response and/or growth potential of a transgenic plant comprising said nucleotide sequence.

The specification as filed describes isolation of a nucleotide sequence (SEQ ID NO: 1) encoding a ROB5 protein as defined in SEQ ID NO: 2. The nucleotide sequence was isolated through screening an expression cDNA library prepared from Broom grass cells (Examples 1 and 2). The specification further describes frost, heat and drought tolerant canola, flax and potato plants expressing said nucleotide sequence. The specification further describes that said transgenic plants exhibited faster germination and seedling emergence compared to an untransformed control plant. Furthermore, specification also describes that said transgenic plants matured earlier compared to untransformed control plants. See pages 36-43, Examples 6-20. Field trial evaluations of said transgenic canola and flax plants are also describes. See pages 45-53.

Claim 1 is directed to an isolated nucleic acid sequence encoding a fragment of any ROB5 protein, claim 1 is also directed to any ROB5 protein, claim 2 is directed to a nucleotide sequence encoding a peptide which has at least 50% sequence identity to the peptide encoded by SEQ ID NO: 1, claim 2 is also directed to a nucleotide sequence encoding a part of protein encoded by SEQ ID NO: 1, claim 3 is directed to a

nucleotide sequence encoding a protein which has at least 70% sequence identity to the protein encoded by SEQ ID NO: 1, claim 4 is directed to a nucleotide sequence encoding a protein which has at least 90% sequence identity to the protein encoded by SEQ ID NO: 1, and claim 5 is directed to a nucleotide sequence encoding a protein which has at least 95% sequence identity to the protein encoded by SEQ ID NO: 1. This implies that these claims and claims dependent thereon encompass nucleotide sequence(s) which would encode protein having less than 100% sequence identity to the ROB5 protein defined in SEQ ID NO: 2. The claims encompass substitutions, additions, deletions of one or more nucleotides in the nucleotide sequence of SEQ ID NO: 1, implying that the encoded proteins derived from such sequence(s) would comprise addition, substitutions or deletions of one or more amino acids in the functionally established ROB5 protein encoded by SEQ ID NO: 1 and further as defined in SEQ ID NO: 2.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and

that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not have adequate written description for genus of a) sequences that have at least 50%-95% sequence identity to SEQ ID NO: 1, b) genus of sequences that have at least 50%-95% sequence identity to the complementary sequence of SEQ ID NO: 1, c) genus of nucleotide sequences encoding ROB5 proteins or fragments thereof, d) genus of sequences that encode any part of the protein encoded by SEQ ID NO: 1, and e) genus of nucleotide sequences that hybridize to SEQ

ID NO: 1 or a complement thereof under current written description guidelines. Specification does not describe these undisclosed structures of Applicant's broadly claimed genus and one skilled in the art cannot reliably predict the structure of these sequences based upon the disclosure of SEQ ID NO: 2 encoding ROB5 protein of SEQ ID NO: 2.

Furthermore, said structures of Applicant's broadly claimed genus are not correlated to the function of altering a stress response and/or growth potential in a transgenic plant. Further, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures of their broadly claimed genus. Applicants have failed to reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-8, 10, 12-17, 20-24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (The Plant Cell, 10:1391-1406, August 1998).

Liu et al. disclose a drought or low temperature tolerant transgenic plant and a method of producing said transgenic plant by transforming the cell with a recombinant polynucleotide operably linked to the constitutive CaMV 35S promoter or rd29A stress inducible promoter, said polynucleotide comprising a sequence encoding the DREB1A C-repeat/DRE binding factor (CBF)-related polypeptide and expressing said CBF-related polypeptide in the transformed *Arabidopsis* cell (page 1396 column 2 - page 1398 column 2).

The property of hybridizing to a nucleotide sequence under stringent conditions is inherent to the nucleotide sequence disclosed in the reference. The property of improved growth potential is also inherent to the nucleotide sequence disclosed in the reference.

This rejection is made due to following reasons: a) a fragment of ROB5 protein reads on 2 amino acid long peptide of CBF disclosed in the reference (claim 1), b) a complement of SEQ ID NO: 1 reads on 2-mer of the nucleotide sequence encoding CBF disclosed in the reference (claims 2-6), c) the nucleotide sequence disclosed in the reference would hybridize to instant SEQ ID NO: 1 under the stringent conditions recited

in claim 6, and (d) Liu et al. sequence comprises primer(s) that would anneal to instant SEQ ID NO: 1 at low annealing temperature. The "hybridization" recited in claim 28 would encompass any annealing temperature.

Accordingly, Liu et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (The Plant Cell, Vol. 10, 1391-1406, August 1998) in view of Moloney et al. (Plant Cell Reports, 8:238-242, 1989).

Liu et al. teach a drought or low temperature tolerant transgenic plant and a method of producing said transgenic plant by transforming the cell with a recombinant polynucleotide operably linked to the constitutive CaMV 35S promoter or rd29A stress inducible promoter, said polynucleotide comprising a sequence encoding the DREB1A C-repeat/DRE binding factor (CBF)-related polypeptide and expressing said CBF-related polypeptide in the transformed *Arabidopsis* cell (page 1396 column 2 - page 1398 column 2).

Liu et al. do not teach transgenic vegetable species, such as canola plant.

Moloney et al. teach a method of transformation to produce transgenic rapeseed plant, and assert that *Brassica napus* is a major crop, with a worldwide value as an oilseed in excess of $5 billion per annum (pages 238-241).

It would have been prima facie obvious to one of ordinary skill in the art at the time claimed invention was made to use the method of rapeseed transformation as taught by Moloney et al. to transfer and express a CBF sequence as taught by Liu et al. and produce a transgenic rape plant overexpressing CBF. One would have been motivated to produce transgenic rapeseed given the economic importance of this seed crop as asserted by Moloney et al.

Thus, the claimed invention as a whole was prima facie obvious over the combined teachings of the prior art.

Conclusions

12. Claims 1-10, 12-24 and 27-30 are rejected.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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